Association of Food and Drug Officials

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September 13, 2002

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 02N-0209 Governing First Amendment Case Law

The Association of Food and Drug Officials Board of Directors, hereinafter referred to as AFDO, is pleased to offer comments on the Food and Drug Administration's (FDA) Docket No. 02N-0209.

AFDO is a 106 year-old organization that represents federal, state, and local government regulatory officials and industry associates, many of whom are involved with public health safety efforts focusing on foods, drugs, biologics and devices.

There is nothing in the First Amendment that protects false, untruthful, or misleading commercial speech. To this end, the regulations of the FDA must protect consumers from commercial speech that is false or misleading in any particular. Where specialized knowledge, such as that of a doctor, pharmacist, or health practitioner, is required for the safe and effective use of a product, particularly a product with public health and safety ramifications, AFDO considers it necessary for FDA to regulate that speech in a manner to reduce the risk to consumers of misinformation and/or misdirection which may cause the product to render a health risk.

Commercial speech, labeling, that may be false or misleading in any particular, is generally held to be subject to regulation (limitation) in order that the layperson, purchaser and/or user can have correct information as to the nature of the product and its intended, safe use. Courts have found that failure to disclose information that is material to the nature of the product, its intended safe use, or that may lead to a false or deceptive interpretation of the label information by a layperson, can be regulated commercial speech.

In today's climate where free speech interpretations are being liberalized in many areas, a liberalization of the above interpretations with respect to the regulation of commercial speech related to foods, drugs and dietary supplements should be reviewed cautiously. The FDA is the consumer's advocate and guarantor that labeling provided on foods and drugs is not false or misleading in any particular and for drugs that the product is efficacious as labeled. Among the critical issues that require regulating commercial speech to ensure absence of false or misleading information are: public health issues (therapeutic claims and ingredient concentrations, presence of ingredients not readily identifiable in the finished

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product including ingredients which may be allergens, quality and quantity claims, use of additives, control of deleterious substances through tolerances, etc.) and economic representations (those which relate to possible deceptive formulations, statements, and product label representations).

In answer to specific questions provided in the Request for Comments, the following is provided:

1. Are there arguments for regulating speech about drugs more comprehensively than, for example, about dietary supplements?

There is not a clear line of demarcation between drugs and some highly purified extracts of plant components that are sold as dietary supplements. Many prescription drugs began their life as a plant component and many of these components that become drugs, such as tamoxifen for example, have dangerous side effects if their use is not prescribed and monitored by a physician. For prescription drugs, the doctor and pharmacist serve as gatekeepers for evaluating information as to the characteristics of the drug, including its appropriate use and risks. If these drugs are marketed through advertising directly to consumers, full disclosure of pertinent information for safe and efficacious use of the drugs, including warnings and contraindications, is required through appropriate regulations governing such advertisements.

There is, however, no gatekeeper for dietary supplements and the FDA label requirements should become that gatekeeper in a fashion similar to over-the-counter (OTC) drugs. For the safe and efficacious use of dietary supplements, FDA must regulate the use, labeling and advertising, such as active ingredient strength, ingredients, appropriate warnings, contraindications and adverse events, as is currently required for OTC drugs and prescription drugs

FDA should especially consider increased regulation of commercial speech for dietary supplements that are concentrated, refined extracts more in line with OTC label requirements as opposed to those supplements that are in their natural state with lower, naturally occurring active ingredient strengths. The concentrated forms frequently represent greater need for disclosure with respect to contraindications and adverse event warnings and other information for safe and efficacious use. It should be noted that currently the FDA does not regulate the commercial speech or advertising for dietary supplements in a manner that ensures safety for the consumers with respect to contraindications and warning statements on dietary supplements.

2. What are the positive and negative effects, if any, of industry's promotion of prescription drugs, biologics and/or devices?

Manufacturers that do direct-to-consumer advertising have met different standards for their products. They have had to establish and prove safety and effectiveness for their products, unlike pharmacists that are compounding and/or manufacturing products and

then advertising them to practitioners and consumers. Also, advertisements/promotions cross international boundaries creating problems for Mexico and Canada specifically.

Negative effects are persons self diagnosing and buying these drugs over the Internet or in foreign countries with no medical oversight. They also demand certain drugs from their physician which interferes with the judgment of the physician.

Positive effects are persons are better informed on the array of drugs available for various conditions.

3. May FDA distinguish claims concerning conventional foods from those relating to dietary supplements, taking into account limits on claims that can be made about foods in the Nutrition Labeling and Education Act, 21 U.S.C. 301, 321, 337, 343, 371?

AFDO believes that FDA must do this based on the fact that by definition, dietary supplements may be concentrated extracts of plant products with significant biological activity and impact—a fact that is not true of traditional foods. Such information can be provided in tabular form and/or in concise messages regarding any public health concern that is present or that consumers need to know to evaluate appropriate and safe use prior to product purchase. AFDO believes that a significant number of consumers approach dietary supplements as alternatives to therapy by drugs. Therefore, there is a basis to approach dietary supplement and conventional foods somewhat differently.

4. Should disclaimers be required to be in the same (or smaller or larger) size of type and given equal prominence with claims?

It would be advisable to utilize a consumer focus group that includes a cross section of potential users—particularly senior citizens—to determine the need for qualifiers and/or disclaimers. Need for the use of disclaimers should be minimized. Type size should be sufficient to provide the information and any qualifier so that one does not take precedent over the other. Some research may be available from the Federal Trade Commission gathered as a result of advertising-impact investigations.

5. How can warnings be made most effective in preventing harm while minimizing the chances of consumer confusion or inattention?

AFDO believes the OTC drug monographs provide a good template for consumer information on warning statements. Clear concise warning in plain English and in a reasonable type size for age and/or other impaired sight is needed. In other words, it has to be easily readable and understandable by the intended consumer. Another effective method is similar to standardized panels found on foods pursuant to the Nutritional Labeling and Education Act and the panels on OTC drugs.

6. What arguments or social science evidence, if any, can be used to support distinguishing between claims made in advertisements and those made on labels?

None, AFDO believes that because advertising is frequently done in "sound bites", whereas labeling stays with the product, there is a strong need to control advertising to the same degree as labeling with respect to information, except directions for use which should be clearly defined on the label. The FDA, as gatekeeper for the safety and health-education of citizens, has a strong role to play with both labels and advertising. Advertising is labeling of the product.

7. Would permitting speech by manufacturer, distributor, and marketer about off-label uses undermine the act's requirement that new uses must be approved by the FDA?

To begin with, most distributors and marketers have no knowledge, training, or licensure that qualifies them to provide information regarding off-label uses. Off-label uses to be recommended to consumers not only undermines the FDA's authority, but also would serve to encourage abuse--possibly dangerous abuse of products. Off-label use speech should be limited to physicians who must then assume liability for the consequences of any off label prescribing.

8. Do FDA's speech-related regulations advance the public health concerns they are designed to address?

YES! Alternative approaches would undermine the very purpose and essence of the Federal Food, Drug and Cosmetic Act that serves to protect public health and ensure consumers of accurate and truthful information that is not misleading in any particular. One of the basic powers of government is to protect public health and well-being and this Act is a cornerstone to fulfilling that role.

9. Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?

Regulation under the original Pure Food Act and the Food Drug and Cosmetic Act has provided almost 100 years of gold-standard regulation of foods and drugs. AFDO favors giving FDA full support for effective enforcement of these requirements through increased resources to the agency. This is particularly true in the areas where FDA has had to "back off" because of lack of resources.

AFDO hopes that these comments enforce to the FDA our position that, in order to provide adequate consumer protection, FDA must be a strong consumer advocate for public health safety and accurate information regarding the products being regulated. We appreciate and thank you for the opportunity to comment on this issue.

Sincerely,

Shirley A Baker

President
Association of Food & Drug Officials

AFDO Memorandum

7316 '02 17 :30

To: Docket Management Office
From: Shirley Bortner
Date: 9/16/02
Re: FDA Docket 02N-0209

Enclosed please find a hard copy of comments that were filed electronically on 9/13/02. Please note they were submitted in my name in error. The Commentor should be Ms. Shirley B. Bohm, President.

Thank you.

Shirley Bortner
Support Staff
Association of Food and Drug Officials

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